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September 2, 2026

VIA ECF
Lyle W. Cayce
Clerk of Court
United States Court of Appeals, Fifth Circuit
F. Edward Hebert Building
600 S. Maestri Place
New Orleans, Louisiana 70130-3408

Re: *Louisiana v. Food & Drug Administration*, No. 26-30203

Dear Mr. Cayce:

Pursuant to Federal Rule of Appellate Procedure 28(j), Plaintiffs respectfully submit the Northern District of Texas's opinion in *Florida v. U.S. Food & Drug Administration*, No. 7:25-CV-00126-O (N.D. Tex. August 30, 2026) (Op.), which is attached to this letter. *Florida* presents a sweeping challenge to the federal government's mifepristone regulations, including, as here, the 2023 REMS's permanent removal of the in-person dispensing requirement. There, as here, the Manufacturers intervened as defendants. And there, as here, the Manufacturers and the federal government challenged the plaintiff States' standing.

The district court rejected that standing challenge. It explained that district courts in this circuit are "bound by" *Louisiana v. Food & Drug Administration*, 175 F.4th 310 (5th Cir. 2026). Op.6. The district court also recognized that arguments like those at issue in this case "are clearly foreclosed in light of the Fifth Circuit's ruling in *Louisiana*." Op.7. Specifically, the court explained that "the actual expenditure of Medicaid funds to treat adverse events suffered by women as a result of FDA-approved abortion drugs" is alone sufficient to establish standing. *Id.* Similarly, the court explained that "preempting the States' abortion regulations" and "inhibiting the States' ability to enforce those

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regulations" likewise constitute "sovereign injuries support[ing] standing." *Id.*

To be sure, the merits panel in this case is not similarly bound by *Louisiana* itself. But the rules on which *Louisiana* is based are themselves binding: "A State's [Medicaid] 'expenditures in providing emergency medical services' constitute an injury for standing purposes," *Louisiana*, 175 F.4th at 319–20 (citing *Texas v. United States*, 50 F.4th 498, 518 (5th Cir. 2022), and "Louisiana has a 'sovereign interest in the power to create and enforce a legal code,'" *id.* at 318, 319 (citing *Texas v. United States*, 809 F.3d 134, 153 (5th Cir. 2015)). *Florida* confirms that the law is firmly on Plaintiffs' side: They are backed not only by *Alliance I* and *Alliance II*, but also by *Louisiana* and its cited precedents—and now a district court decision implementing *Louisiana*. Those are especially good reasons to follow *Louisiana*.

Word Count: 342

Respectfully,

/s/J. Benjamin Aguiñaga
J. Benjamin Aguiñaga
Solicitor General

Counsel for Louisiana

/s/Erin M. Hawley
Erin M. Hawley

Counsel for Louisiana and Rosalie Markezich

cc: All Counsel (via ECF)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
WICHITA FALLS DIVISION

THE STATE OF FLORIDA, ET AL.,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	**Civil Action No. 7:25-CV-00126-O**
	§	
U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,	§	
	§	
Defendants.	§	

OPINION & ORDER

Before the Court are Defendants Food and Drug Administration, Robert F. Kennedy, Jr, Martin A. Makary, Richard Pazdur, and Department of Health and Human Services' ("Government Defendants") Motion to Stay or Alternatively to Dismiss (ECF No. 20); Danco Laboratories, LLC and GenBioPro, Inc.'s Motions to Dismiss (ECF Nos. 52, 54); The State of Florida and the State of Texas's Consolidated Response (ECF No. 56); and Defendants' Replies (ECF Nos. 57–59). Having considered the Motions, briefing, and applicable law, the Court **DENIES** Danco Laboratories, LLC and GenBioPro, Inc.'s Motions to Dismiss and **GRANTS** in part Government Defendants' Motion to Stay.

I. BACKGROUND[1]

Under federal law, the purpose of the United States Food and Drug Administration ("FDA") is to ensure that drugs on the market are safe and effective. The State of Florida and the State of Texas ("Plaintiffs") allege that the FDA has contravened that purpose by taking unlawful agency action concerning two drugs: mifepristone and misoprostol. These drugs are used to

[1] Unless otherwise cited, the Court's recitation of the facts is taken from Plaintiffs' Complaint. *See* Compl., ECF No. 1.

accomplish chemical abortions. Mifepristone blocks progesterone receptors in the uterus, causing the uterine lining to breakdown. Without this lining providing necessary sustenance to the baby, the baby dies. Misoprostol then induces cervical dilation and uterine contractions to expel the deceased baby from the womb. Plaintiffs allege that these drugs frequently send women to the emergency room with hemorrhaging, sepsis, and other complications, and sometimes kill women.

In 2000, under President Clinton, FDA approved mifepristone using the brand name "Mifeprex" under Title 21, Part 314, Subpart H of the Code of Federal Regulations ("the 2000 Approval"). The FDA conditioned the approval on a protocol—later converted into a risk evaluation and mitigation strategy ("REMS")—that included, among other things, a restriction to pregnancies through 49 days' gestation; a requirement that abortion drugs be dispensed and administered in person by a physician capable of accurately assessing gestational age, diagnosing ectopic pregnancies, and providing surgical intervention; a minimum of three office visits; and a requirement to report any hospitalization, transfusion, or other serious event.

In 2016, under President Obama, FDA changed mifepristone's REMS by extending the maximum gestational age from 49 to 70 days, allowing non-physicians to dispense and administer abortion drugs, eliminating the requirement that misoprostol administration occur in-clinic, removing in-person follow-up examination requirements, and relieving physicians of their obligation to report non-fatal complications ("the 2016 Changes").

In 2021, under President Biden, FDA announced it would no longer enforce the in-person dispensing requirement for mifepristone and eliminated the requirement entirely in 2023 ("the 2021/2023 Dispensing Changes"). These actions led to the approval of generic versions of mifepristone in 2019 and 2025 ("the Generic Approvals"). Plaintiffs allege that each of these actions ("the Challenged Actions") was illegal under the Administrative Procedure Act ("APA"),

the Federal Food, Drug, and Cosmetic Act ("FFDCA"), the Pediatric Research Equity Act ("PREA"), and the Comstock Act.

On December 9, 2025, Plaintiffs filed their complaint against the FDA, FDA Commissioner Martin A. Makary, the Department of Health and Human Services ("HHS"), HHS Secretary Robert F. Kennedy, and the director of the Center for Drug Evaluation and Research. On April 10, 2026, the Court granted motions to intervene and permitted motions to dismiss to be filed by two of the three FDA-approved manufacturers of mifepristone: Danco Laboratories, LLC ("Danco") and GenBioPro, Inc. ("GenBioPro") (collectively, "Intervenor Defendants"). The Government Defendants filed a motion to stay or, alternatively, dismiss. The motions have been briefed and are now ripe for the Court's review.

II. LEGAL STANDARD

Federal courts are courts of limited jurisdiction and must have "statutory or constitutional power to adjudicate the case." *Home Builders Ass'n of Miss. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998). "Under the Constitution's Article III cases and controversies requirement, a plaintiff must establish standing to sue. Standing requires: (1) an injury in fact, (2) a sufficient 'causal connection between the injury and the conduct complained of' and (3) a likelihood that the injury will be redressed by a favorable decision." *Morgan v. Huntington Ingalls, Inc.*, 879 F.3d 602, 606 (5th Cir. 2018) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992); U.S. CONST. art. III, § 2. The injury cannot be merely "conjectural or hypothetical." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009). Causation requires that the injury "fairly can be traced to the challenged action of the defendant" rather than to "the independent action of some third party not before the court." *Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 41–42 (1976). "'[W]hen standing is challenged on the basis of the pleadings,' [courts] must 'accept as true all material

allegations of the complaint and . . . construe the complaint in favor of the complaining party.'" *Ass'n of Am. Physicians & Surgeons, Inc. v. Tex. Med. Bd.*, 627 F.3d 547, 550 (5th Cir. 2010) (quoting *Pennell v. City of San Jose*, 485 U.S. 1, 7 (1988)) (first alteration and omission in original).

A Rule 12(b)(1) motion is proper when the court lacks subject matter jurisdiction, including for lack of standing. FED. R. CIV. P. 12(b)(1). To survive at the pleadings stage, a plaintiff must "allege a plausible set of facts establishing jurisdiction." *Burnett Specialists v. Cowen*, 140 F.4th 686, 693 (5th Cir. 2025) (citation omitted). Under Rule 12(b)(3), once a party moves to dismiss based on improper venue, the plaintiff must "come forward with evidence showing venue is proper." *Perez v. Pan Am. Life Ins. Co.*, 70 F.3d 1268 (5th Cir. 1995) (per curiam). Under Rule 12(b)(6), "where it is evident from the plaintiff's pleadings that the action is [time] barred" dismissal of that claim is proper. *Jones v. Alcoa, Inc.*, 339 F.3d 359, 366 (5th Cir. 2003). The Court must also dismiss any claim which fails to state a claim as a matter of law. *Boudreaux v. Louisiana State Bar Ass'n*, 3 F.4th 748, 753 (5th Cir. 2021).

III. ANALYSIS

A. Intervenor Defendants' Motions to Dismiss

1. Whether Texas is Precluded from Relitigating its Standing.

The Court begins with the threshold inquiry of preclusion. GenBioPro argues that because the Ninth Circuit decided that Texas lacked standing to intervene in *Washington v. FDA*, 108 F.4th 1163 (9th Cir. 2024), the doctrine of res judicata prevents Texas from establishing standing in this case. The Court disagrees.

"The preclusive effect of a judgment is defined by claim preclusion and issue preclusion, which are collectively referred to as 'res judicata.'" *Taylor v. Sturgell*, 553 U.S. 880, 892 (2008).

Standing is a jurisdictional question and when a jurisdictional ruling is claimed to have preclusive effect, "issue preclusion is the better framing." *Bank of Louisiana v. Fed. Deposit Ins. Corp.*, 33 F.4th 836, 838 (5th Cir. 2022). Issue preclusion differs from claim preclusion in that "it is an equitable doctrine which should be 'applied only when the alignment of the parties and the legal and factual issues raised warrant it.'" *Copeland v. Merrill Lynch & Co.*, 47 F.3d 1415, 1423 (5th Cir. 1995) (quoting *Nations v. Sun Oil Co.,* 705 F.2d 742, 744–45 (5th Cir.) (en banc). A district court has broad discretion to determine when issue preclusion, particularly the type of offensive preclusion at issue here, should be applied. *Id.*

A suit that has been dismissed for lack of standing does not "make the case res judicata on the substance of the asserted claim." *Boone v. Kurtz*, 617 F.2d 435, 436 (5th Cir. 1980) (per curiam). "If the jurisdictional problem is later fixed, the suit can be refiled." *Bank of Louisiana*, 33 F.4th at 838; *see also Lopez v. Pompeo*, 923 F.3d 444, 447 (5th Cir. 2019) (explaining that when a court "dismisses a case due to failure of one particular jurisdictional element, and the party later cures that jurisdictional defect and brings a new suit, res judicata does not bar the second suit"). Critically, "preclusion cannot apply to factual findings that were never actually litigated." *Lartigue v. Northside Indep. Sch. Dist.*, 100 F.4th 510, 522 (5th Cir. 2024).

Moreover, "issue preclusion requires . . . identical issues." *Students for Fair Admissions, Inc. v. Univ. of Texas at Austin*, 37 F.4th 1078, 1089 n.16 (5th Cir. 2022). The Fifth Circuit has held that the "'relitigation of an issue is not precluded unless the facts and the legal standard used to assess them are the same in both proceedings.'" *Pace v. Bogalusa City Sch. Bd.*, 403 F.3d 272, 290 (5th Cir.2005) (quoting *Southmark Corp. v. Coopers & Lybrand (In re: Southmark Corp.)*, 163 F.3d 925, 932 (5th Cir.1999)). Further, "[i]ssues of fact are not 'identical' or 'the same,' and

therefore not preclusive, if the legal standards governing their resolution are 'significantly different.'" *Id.* (citations omitted).

Here, the legal standard governing standing in the context of Texas's asserted causes of action is significantly different from the one used in *Washington*. *See Montana v. United States*, 440 U.S. 147 (1979) (asking "whether controlling facts or legal principles ha[d] changed significantly" since a judgment before giving it preclusive effect). The Fifth Circuit recently found that the State of Louisiana had standing to challenge the 2023 REMs on substantially similar grounds to those Texas now alleges. *See generally Louisiana by & through Murrill v. Food & Drug Admin.*, 175 F.4th 310 (5th Cir. 2026). The Court is bound by the Fifth Circuit's holding and must apply the legal reasoning set out in *Louisiana* when evaluating Texas's standing. *Perez v. Abbott*, 250 F. Supp. 3d 123, 139 (W.D. Tex. 2017) ("[A] district court is bound by a circuit decision unless or until it is overturned by an en banc decision of the circuit court or a decision of the Supreme Court.").

Thus, this Court must apply the Fifth Circuit's standing analysis from *Louisiana* instead of the standing analysis used by the Ninth Circuit's *Washington*. These two standards are significantly different from one another and because much has changed since *Washington* was decided, issue preclusion does not bar Texas from relitigating its standing to contest the Challenged Actions before this Court. *See Commissioner v. Sunnen*, 333 U.S. 591, 599 (1948) (issue preclusion "is designed to prevent repetitious lawsuits over matters which have once been decided and which have remained substantially static, factually and legally").

2. Whether Plaintiffs Have Standing.

The Intervenor Defendants jointly challenge Texas and Florida's Article III standing to bring their claims. They argue that the Challenged Actions did not cause the States' alleged

economic, sovereign, or quasi-sovereign injuries. The Court disagrees and finds that the majority of the Intervenor Defendants' arguments are clearly foreclosed in light of the Fifth Circuits ruling in *Louisiana*. *See generally* 175 F.4th 310 (5th Cir. 2026).

First, Plaintiffs' allege two forms of economic injury: (1) the actual expenditure of Medicaid funds to treat adverse events suffered by women as a result of FDA-approved abortion drugs;[2] and (2) costs incurred to investigate and prosecute mail-order abortions.[3] The Fifth Circuit has held that state-incurred Medicaid costs caused by women who needed emergency care from complications resulting from out-of-state mifepristone is sufficient to establish economic injury. *Id.* at 320. Here, Plaintiffs have alleged facts linking concrete Medicaid costs to care stemming from out-of-state mifepristone.[4] That "alone [is] sufficient to establish [Plaintiffs'] standing." *Id.*

Likewise, Plaintiffs alleged sovereign injuries support standing. Plaintiffs argue that the Challenged Actions injure the States' sovereign interest in creating and enforcing their legal codes in two ways: (1) by preempting the States' abortion regulations; and (2) by inhibiting the States' ability to enforce those regulations.[5] The *Louisiana* court held that the 2021/2023 Dispensing Changes "cause[] 'federal interference with the enforcement of [Louisiana] law,' which gives Louisiana standing to challenge it." *Id.* at 319 (quoting *Texas v. United States ("DAPA")*, 809 F.3d 134, 153 (5th Cir. 2015)). So too here. Plaintiffs' laws are substantially similar to Louisiana's and the injury incurred by 2021/2023 Dispensing Changes is the same. *See* Fla. Stat. § 390.0111(1); Fla. Stat. § 390.0111(10)(a); Tex. Penal Code § 1.07(26); Tex. Health & Safety Code § 171.063(b-1). As the Fifth Circuit noted, the 2021/2023 Dispensing Changes "sanction[] and facilitate[]

[2] Compl. ¶¶ 285–90, ECF No. 1.
[3] *Id.* ¶¶ 299–304.
[4] *Id.* at ¶¶ 287–89.
[5] Resp. 14–16, ECF No. 56.

conduct with the express purpose of undermining [Plaintiffs'] legal restrictions on abortion." *Louisiana*, 175 F.4th at 319.

Intervenor Defendants argue that the *Louisiana* court's failure to consider standing with regard to the other Challenged Actions aside from the 2021/2023 Dispensing Changes is fatal.[6] Such contestation is unavailing. Plaintiffs need not show that each of the Challenged Actions independently caused their injury. For the reasons discussed *supra*, the 2021/2023 Dispensing Changes caused Plaintiffs' injury. At this stage, it is sufficient to confer standing for Plaintiffs to allege that the 2000 Approval and 2016 Major Changes exacerbated that injury.[7] *See Texas v. United States ("DACA")*, 50 F.4th 498, 519 (5th Cir. 2022) ("DACA is not the sole cause of the State's injury, but DACA has exacerbated it. That is sufficient."); *see also Louisiana v. EEOC*, 705 F. Supp. 3d 643, 653–54 (W.D. La. 2024) (if states "have unambiguously expressed their opposition to purely elective abortions by passing laws prohibiting the same," then "the principles of federalism" "clearly" give the states Article III standing to challenge a federal agency's intrusion upon that sovereign prerogative).

Finally, Plaintiffs also allege a quasi-sovereign injury—a question unaddressed in *Louisiana*. Intervenor Defendants argue that Plaintiffs cannot assert their quasi-sovereign interests in this case because, under the *Mellon* bar, "a 'State does not have standing as *parens patriae* to bring an action against the Federal Government.'"[8] Plaintiffs respond that the *Mellon* bar only applies when a state attempts to bring an action on behalf of United States citizens against the

[6] *See* GenBioPro's Reply 5–8, ECF No. 59; *see also* Danco's Br. Supp. Mot. Dismiss 9, ECF No. 53.
[7] Danco's Br. Supp. Mot. Dismiss 9, ECF No. 53 (conceding that the States' Medicaid reimbursements are traceable to the 2000 Approval); *see also* Compl. ¶¶ 238–64, ECF No. 1 (explaining how the 2016 Major Changes made abortion drugs more dangerous).
[8] Danco's Br. Supp. Mot. Dismiss 15, ECF No. 53 (quoting *Haaland v. Brackeen*, 599 U.S. 255, 295 (2023)); *see also* GenBioPro's Br. Supp. Mot. Dismiss 14, ECF No. 55.

federal government.[9] They further argue that because they assert a quasi-sovereign interest in protecting the health and safety of both pregnant women and preborn children from abortion drugs and the latter are not recognized as United States citizens, *Mellon* does not apply.[10] The Court agrees.

The Supreme Court has instructed that to have *parens patriae* standing a state must assert an injury to their "quasi-sovereign" interest. *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 600–01 (1982). "Quasi-sovereign interests defy easy exemplification, but the Supreme Court defined them as a state's interests 'in the health and well-being—both physical and economic—of its residents in general,' as well as a state's 'interest in not being discriminatorily denied its rightful status within the federal system.'" *Texas v. Becerra*, 577 F. Supp. 3d 527, 558 (N.D. Tex. 2021) (quoting *Alfred L. Snapp*, 458 U.S. at 607).

In *Massachusetts v. Mellon*, the Supreme Court made clear that states do not have *parens patriae* standing to protect their citizens from the operation of federal law. 262 U.S. 447, 485 (1923). But as the Supreme Court has explained, *Mellon* did not adopt a broad bar on *parens patriae* standing because the *Mellon* court was not "called upon to adjudicate . . . *quasi-sovereign rights actually invaded or threatened.*" *Massachusetts v. E.P.A.*, 549 U.S. 497, 520 n.17 (2007) (emphasis in original). The *Massachusetts* court held that there was a "critical difference between allowing a State 'to protect her citizens from the operation of federal statutes' (which is what *Mellon* prohibits) and allowing a State to assert its rights under federal law (which it has standing to do)." *Id.* (citing *Georgia v. Pa. R. Co.*, 324 U.S. 439, 447 (1945)).

With that understanding in mind, the Court holds that Plaintiffs have *parens patriae* standing to contest the Challenged Actions. Plaintiffs assert a quasi-sovereign interest in

[9] Resp. 19–20, ECF No. 56.
[10] *Id.*

protecting the health and safety of both pregnant women and preborn children from abortion drugs. Plaintiffs have provided evidence that *inter alia* "as many as 20% of women who take mifepristone suffer a serious adverse event, and the FDA's own label estimates that one in every 25 users will need to visit the emergency room."[11] Plaintiffs have also shown that "chemical abortions claim the lives of tens of thousands of preborn children in Florida and Texas each year."[12]

Plaintiffs have a right to vindicate their interests "in the health and well-being—both physical and economic—of [their] residents in general." *Alfred L. Snapp*, 458 U.S. at 607. It is difficult to imagine what could be more integral to a population's health and well-being than maternal health and, in the case of the preborn, life itself.[13] Such interests are sufficient to confer *parens patriae* standing. *See Becerra*, 577 F. Supp. 3d at 559 (approving Texas's standing to bring APA claims against an HHS mask and vaccine mandate due to its "*parens patriae* interest in protecting the welfare of its neediest children").

Second, even if the *Mellons* bar prohibited Plaintiffs from bringing a lawsuit on behalf of citizen mothers, it would not apply to the preborn. Intervenor Defendants urge the Court to reject the preborn as a "non-existent exception" to the *Mellon* bar "that the federal government has not itself recognized."[14] *But see Alfred L. Snapp*, 458 U.S. at 607 ("[T]he articulation of such [quasi-sovereign] interests is a matter for case-by-case development[.]"). However, Intervenor Defendants misunderstand the logic of *Mellon*. The *Mellon* court held that a state cannot sue as *parens patriae* "to protect her citizens from the operation of federal statutes" because the citizens of states are also citizens of the United States. 262 U.S. at 485–86. The Supreme Court continued,

[11] *See* Compl. ¶¶ 4–6, ¶¶ 206–23, ECF No. 1.
[12] *Id.* at ¶¶ 429–30.
[13] *See* Emer de Vattel, THE LAW OF NATIONS, Ch. II § 17 (1758) ("If a nation is obliged to preserve itself, it is no less obliged carefully to preserve all its members. The nation owes this to itself, since the loss even of one of its members weakens it, and is injurious to its preservation.").
[14] GenBioPro's Reply 6, ECF No. 59.

when a citizen of the United States seeks to enforce their rights under the statutes thereof, it is the federal government, not the states that represent them *parens patriae* and "they must look for such protective measures as flow from that status." *Id.*

Here, the United States, as such, offers no protective measures to the preborn because the federal government has no view as to their status. *See Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215, 263 (2022) (expressing no "view about if and when prenatal life is entitled to any of the rights enjoyed after birth").[15] And yet the states have an interest in protecting fetal life, as Intervenor Defendants concede.[16] *Id.* at 264–63; *see also CASA, Inc. v. Trump*, 793 F. Supp. 3d 687 (D. Md. 2025) (finding that class representatives, which included "future children" had standing against the federal government); 1 William Blackstone, COMMENTARIES *130 ("An infant *in ventre sa mere,* or in the mother's womb, is supposed in law to be born for many purposes.").

It follows then that states can have standing as *parens patriae* to protect the well-being of their preborn inhabitants. *See State of Missouri v. State of Illinois*, 180 U.S. 208, 241 (1901) ("[I]t must surely be conceded that, if the health and comfort of the inhabitants of a state are threatened, the state is the proper party to represent and defend them."). Both Plaintiffs have attempted to address the harms posed to mother and child by enacting laws preventing elective abortions but these attempts have been undermined by the Challenged Actions.[17] *See Alfred L. Snapp*, 458 U.S.

[15] It should be noted that unlike in other circumstances involving non-citizens, the federal government provides no legal rights to the preborn. Contrast this with say, the immigration context. States would not have standing to sue on behalf of their non-citizen alien inhabitants because federal law has preempted state law with respect to immigration status. *See generally Arizona v. United States*, 567 U.S. 387 (2012). Thus, the rights of aliens, legal or illegal, stem from the federal government and the *Mellon* bar would apply. *See* 262 U.S. 485–86.

[16] *See* GenBioPro's Reply 6, ECF No. 59 (quoting *Washington v. U.S. Food & Drug Admin.*, 108 F.4th 1163 (9th Cir. 2024) ("[Texas] has a legitimate interest in legislating to protect maternal health and fetal life[.]").

[17] *See* Compl. ¶¶ 311–24, ECF No. 1.

at 607 ("One helpful indication in determining whether an alleged injury to the health and welfare of its citizens suffices to give the State standing to sue as *parens patriae* is whether the injury is one that the State, if it could, would likely attempt to address through its sovereign lawmaking powers.").

Each alleged injury is traceable to the Challenged Actions and is redressable by setting them aside. Accordingly, the Court finds that Plaintiffs' have Article III standing to contest the Challenged Actions.

3. Whether Plaintiffs are Within the Zones of Interest.

Intervenor Defendants argue that Plaintiffs are outside the zone of interests of the FFDCA, the PREA, and the Comstock Act.[18] Plaintiffs suing under the APA must assert an interest that is "arguably within the zone of interests to be protected or regulated by the statute that they say was violated." *DAPA*, 809 F.3d at 162 (internal marks omitted). The zone-of-interests test "is not meant to be especially demanding" and is applied "in keeping with Congress's evident intent when enacting the APA to make agency action presumptively reviewable." *Id.* (internal marks omitted). The zone-of-interests test "looks to the law's substantive provisions to determine what interests (and hence which plaintiffs) are protected." *Simmons v. UBS Fin. Servs., Inc.*, 972 F.3d 664, 669 (5th Cir. 2020). "That interest, at times, may reflect aesthetic, conservational, and recreational as well as economic values." *Ass'n of Data Processing Serv. Orgs., Inc. v. Camp*, 397 U.S. 150, 154 (1970).

"The test forecloses suit only when a plaintiff's interests are so marginally related to or inconsistent with the purposes implicit in the statute that it cannot reasonably be assumed that Congress intended to permit the suit." *DAPA*, 809 F.3d at 162 (internal marks omitted). In other

[18] *See e.g.*, Danco's Br. Supp. Mot. Dismiss 16–18, ECF No. 53

words, "[t]here is no presumption against judicial review and in favor of administrative absolutism unless that purpose is fairly discernible in the statutory scheme." *Camp*, 397 U.S. at 157 (internal marks omitted); *see also Barlow v. Collins*, 397 U.S. 159, 165 (1970) (courts "must decide if Congress has in express or implied terms precluded judicial review or committed the challenged action entirely to administrative discretion").

Here, Plaintiffs' interests are more than "marginally related" to the purposes of the relevant statutes. Beginning with the FFDCA, the purpose of the statute's substantive provisions is to "protect the public health" by "assur[ing] the safety, effectiveness, and reliability of drugs." Pub. L. No. 87-781, 76 Stat. 780 (1962); see also 21 U.S.C. § 355. Plaintiffs' clearly share this interest. *See BST Holdings, LLC v. OSHA*, *United States Dep't of Lab.*, 17 F.4th 604, 618 (5th Cir. 2021) ("The States, too, have an interest in seeing their constitutionally reserved police power over public health policy defended from federal overreach."). Both Texas and Florida dedicate a chapter of their codes to regulating drugs and cosmetics. See Fla. Stat. § 499.001; Tex. Health & Safety Code § 431.001. For the same reasons, this interest also places Plaintiffs within the zone of interests for the PREA, which exists to ensure the safety of drugs consumed by minors. *See* 21 U.S.C. § 355c.

Likewise with the Comstock Act, which "indicates a national policy of discountenancing abortion as inimical to the national life." *Bours v. United States*, 229 F. 960, 964 (7th Cir. 1915); *see also Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 70 n.19 (1983) (the "thrust" of the Act was "to prevent the mails from being used to corrupt the public morals"). Florida and Texas have similar interests in promoting public morals, *see Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 569 (1991), and protecting preborn life, *see Dobbs*, 597 U.S. at 262. This confluence of interests is sufficient to overcome the "not especially demanding" zone-of-interests test. *DAPA*, 809 F.3d at 162 (internal marks omitted).

4. Whether Plaintiffs Exhausted Their Administrative Remedies.

Intervenor Defendants next contend that the Complaint should be dismissed under Rule 12(b)(6) because Plaintiffs failed to first present their arguments to FDA through a citizen petition.[19] The Fifth Circuit has repeatedly rejected this argument. *Louisiana*, 175 F.4th at 318 (citing *All. for Hippocratic Med. v. Food & Drug Admin. ("Alliance I")*, No. 23-10362, 2023 WL 2913725, at *15–*16 (5th Cir. Apr. 12, 2023); *All. for Hippocratic Med. v. U.S. Food & Drug Admin. ("Alliance II")*, 78 F.4th 210, 255 (5th Cir. 2023)) (holding that exhaustion was not required because Louisiana's claims were "properly exhausted" as FDA remains "committed to implementing" the 2021/2023 Dispensing Changes). So too does this Court. Intervenor Defendants do not give reason to think that FDA would administratively stay any of the Challenged Actions.[20]

Moreover, the Court is persuaded by the D.C. District Court's ruling in *Vanda Pharms. Inc. v. FDA*. No. 23-CV2812 (CRC), 2024 WL 4133623 (D.D.C. Sept. 10, 2024). There the court found that on "their own terms, the FDA regulations specify that a person . . . who 'asks to participate . . . in a court action' can sue in court as soon as there is a final administrative decision on any [citizen] petition filed under § 10.25(a)—even if the 'interested person' suing is not the one who filed the initial petition." *Id.* at *16. Here, the FDA has already rejected citizen petitions complaining of each of the Challenged Actions before Plaintiffs filed suit.[21] *See* Students for Life, FDA-2023-P-1528 (Jan. 15, 2025). Thus, 21 C.F.R. § 10.45(b) does not require Plaintiffs to file a redundant citizen petition before seeking judicial review.

[19] *See* Danco's Br. Supp. Mot. Dismiss 18–20, ECF No. 53; GenBioPro's Br. Supp. Mot. Dismiss 16–19, ECF No. 53.

[20] The fact that FDA is undergoing a review of the Challenged Actions—the results of which could significantly alter Plaintiffs' claims—does not change the fact that the Challenged Actions remain in effect, particularly in light of *Louisiana* being mere months old and its reasoning having considered the likelihood of an administrative stay.

[21] *See* Compl. ¶¶ 200–04, ECF No. 1.

5. Whether Plaintiffs Claims are Time-Barred.

Penultimately, Intervenor Defendants argue that Plaintiffs' challenges to the approval of mifepristone in 2000 (Count I), the 2016 action (Count II), and the approval of the first generic in April 2019 (Count IV) are barred by the six-year statute of limitations.[22] A claim accrues when the plaintiff has the right to assert it in court— and in the case of the APA, that is when the plaintiff is injured by final agency action." *Corner Post, Inc. v. Bd. of Gov'rs of Fed. Rsrv. Sys.*, 603 U.S. 799, 804 (2024).

First, Plaintiffs' alleged sovereign and quasi-sovereign injuries are dependent upon their restrictions on elective abortions becoming effective—a circumstance that only became possible after June 24, 2022, when the Supreme Court decided *Dobbs*. Florida's sovereign and quasi-sovereign injuries began on May 1, 2024, when its Heartbeat Protection Act took effect.[23] Texas's sovereign and quasi-sovereign injuries began on August 25, 2022, when its Human Life Protection Act became effective, prohibiting abortions from conception.[24] Because it was impossible for Plaintiffs' sovereign and quasi-sovereign injuries to begin before *Dobbs*, Plaintiffs' injuries accrued within the six-year limitation period.[25]

Second, as for Plaintiffs' economic injury, the four corners of the Complaint only contain allegations of increased Medicaid costs within the last six years. At this stage in the proceedings, the Court "is required merely to look to the sufficiency of the allegations of the complaint" to establish jurisdiction. *Paterson v. Weinberger*, 644 F.2d 521, 523 (5th Cir. May 1981). And

[22] *See* Danco's Br. Supp. Mot. Dismiss 20–21, ECF No. 53; GenBioPro's Br. Supp. Mot. Dismiss 19, ECF No. 55.
[23] Compl. ¶ 320, ECF No. 1.
[24] *Id.* at ¶ 323.
[25] *See* Resp. 24 n.13, ECF No. 56 ("Neither law could have been enforced prior to June 24, 2022, when the Supreme Court decided Dobbs. This is why the States 'waited 25 years to challenge the [2000] approval [and] nearly ten years to challenge FDA's 2016 action.'").

Plaintiffs need only "allege a plausible set of facts establishing jurisdiction." *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 652 (5th Cir. 2012). The Court finds that Plaintiffs have met their burden to plausibly allege a set of facts showing an injury that is not time-barred. That is sufficient at the pleadings stage.[26] *Id.*

Plaintiffs' also raise the reopening doctrine to support their argument that the relevant claims are not time-barred. The reopening doctrine "allows a plaintiff to challenge an agency action past the ordinary timeline if the agency substantively reconsiders the original action in a subsequent decision." *Alliance II*, 78 F.4th at 242; *see also Texas v. Biden*, 20 F.4th 928, 951 (5th Cir. 2021) ("If the agency . . . reexamined and reaffirmed its prior decision, the agency's second action (the reaffirmance) is reviewable." (quotation omitted)), *rev'd on other grounds*, 597 U.S. 785 (2022).

Alliance II held that the doctors' challenge to the 2000 Approval was time-barred because "neither the 2016 Amendments nor the 2021 Petition Denial reevaluated FDA's decision in 2000 to approve mifepristone." 78 F.4th at 244. However, the FDA's current review is "evaluating issues . . . ranging from eliminating the REMS entirely to withdrawing the approval of mifepristone for termination of early pregnancy, as well as actions in between."[27] In context, this representation evinces the FDA's "intention to put the [Challenged Actions] back on the chopping block and rethink things." *Biden*, 20 F.4th at 955. The Court therefore finds that Plaintiffs' claims are not time-barred under the reopening doctrine.

[26] *See* Compl. ¶ 287, ¶ 289, ECF No. 1.
[27] Resp. Ex. 1 (Elliott Decl.) ¶ 5, ECF No. 56-1.

6. Whether Plaintiffs' Claims are Ripe.

Finally, Intervenor Defendants dispute that Plaintiffs' claims are ripe in light of FDA's substantive reevaluation of all the Challenged Actions.[28] But in the Fifth Circuit, "disagreements over final, specific agency action[s] are necessarily ripe." *Sierra Club v. Peterson*, 185 F.3d 349, 362 n.16 (5th Cir. 1999); *see also Melissa Indus. Dev. Corp. v. N. Collin Water Supply Corp.*, 256 F. Supp. 2d 557, 567 (E.D. Tex. 2003); *Natural Resources Defense Council, Inc. v. Thomas*, 845 F.2d 1088, 1091 (D.C. Cir. 1988) (ripeness and final agency action "are inextricably intertwined"). No party contests the finality of the Challenged Actions. For that reason, Plaintiffs' claims are ripe. Accordingly, Intervenor Defendants' motions to dismiss are **DENIED**.

B. The Government Defendants' Motion to Stay

Government Defendants move the Court to stay this litigation until after its review of the mifepristone REMS is complete.[29] Plaintiffs respond that "[b]ecause the FDA is substantively reconsidering all the Challenged Actions, the States agree that a time-limited stay would promote 'economy of time and effort for [the Court], for counsel, and for litigants.'"[30] But Plaintiffs "request reasonable parameters for the stay."[31] In light of the parties' limited agreement, the Court finds that a stay is appropriate and **GRANTS** Government Defendants' Motion to Stay in part. To the extent that FDA's motion to dismiss in the alternative seeks dismissal on the grounds already adjudicated above, the motion is **DENIED**.

[28] Danco's Br. Supp. Mot. Dismiss 21–22, ECF No. 53; GenBioPro's Br. Supp. Mot. Dismiss 16–19, ECF No. 55.
[29] Gov. Defs.' Mot. Stay 9, ECF No. 20-1.
[30] Resp. 6, ECF No. 56 (quoting *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936)).
[31] Resp. 6, ECF No. 56.

IV. CONCLUSION

For the foregoing reasons, Intervenor Defendants' Motions to Dismiss (ECF Nos. 52, 54) are **DENIED**. Defendant FDA's Motion to Stay (ECF No. 20) is **GRANTED** in part.

It is **ORDERED** that this action is **STAYED** until the sooner of December 1, 2026 or FDA's completion its review of the Challenged Actions. Within seven days of the stay's expiration, the parties are **ORDERED** to file a joint status report detailing how the case should proceed.

SO ORDERED on this **30th day** of **August, 2026.**

Reed O'Connor
CHIEF UNITED STATES DISTRICT JUDGE